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08/805,813	02/26/97	MITSUHARA	I 085760-000

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EXAMINER

NELSON, A

ART UNIT

PAPER NUMBER

1649

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/805,813

Applicant(s)
Ichiro Mitsuhashi, et al.

Examiner
Amy Nelson

Group Art Unit
1638



☒ Responsive to communication(s) filed on Feb 23, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 21-41 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 21-41 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1638

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.

Claim Objections

2. Claims 31, 40, and 41 are objected to because of the following informalities:

At Claim 23, line 2, "Sarcotoxin" should be changed to --sarcotoxin--.

At Claim 31, line 2, "Cauliflower" should be changed to --cauliflower--.

At Claim 34, line 2, "Sarcotoxin" should be changed to --sarcotoxin--.

At Claim 40, line 2, "Cauliflower" should be changed to --cauliflower--.

At Claim 41, line 2, "resistant" should be changed to --resistance--.

Claim Rejections - 35 USC § 112

3. Claims 21, 22, 24-33, 35-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record set forth in the Official actions mailed 12/16/98 and 7/26/99, as applied to Claims 1-3, 5-

Art Unit: 1638

13, 15, 16, and 18-20. Applicant's arguments filed 2/23/00 have been fully considered but they are not persuasive.

Applicant argues that the standard for determining compliance with the written description requirement is whether the description allows persons of ordinary skill in the art to recognize that Applicant invented the claimed subject matter. Applicant complies with the written description requirement by describing the invention with all its claim limitations. Applicant asserts that the instant specification describes a method of conferring fungal resistance to plants by transformation with an anti-bacterial gene from a Diptera insect, and transgenic plants thereby obtained (response, p. 6-7). Examiner responds that Applicant has not fulfilled the written description requirement for the broad claims. Applicant only describes a single anti-bacterial gene from a Diptera insect, and does not describe any structural characteristics which are distinctive of all anti-bacterial genes from Diptera insects. Therefore, one of skill in the art could not identify other anti-bacterial genes which could be used in the claimed invention, and which are encompassed by the claimed methods and transgenic plants. In order to satisfy the written description requirement, Applicant must describe a representative number of species of the claimed genus, or must describe structural features which are characteristic of most of the species of the claimed genus. Applicant has done neither, and therefore it is not clear that Applicant was in possession of the invention as broadly claimed.

Applicant asserts that the present invention is not directed to a new class of nucleic acids, but rather to the use of a known class of nucleic acids in a novel way, *i.e.* methods for using the

Art Unit: 1638

nucleic acids to confer fungal resistance on plants, and to the transgenic plants. Therefore, Applicant asserts that holding of *Eli Lilly* is not applicable. Further, Applicant asserts that Applicant need not disclose all of the species encompassed by the claimed invention. (response, p. 7-8). Because the nucleic acids are required to practice the claimed methods and to produce the claimed transgenic plants, the same standards for written description which would be applied to the nucleic acids are applicable to the claimed methods/transgenic plants. The decision of the *Eli Lilly* case is indeed applicable to the instant invention because Applicant has not satisfactorily described the claimed genus of nucleic acids. Whereas Applicant need not disclose all of the species encompassed by the claimed genus, Applicant must describe a representative number of species. A single species does not constitute a representative number.

4. Claims 21, 22, 24-33, 35-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to methods of enhancing fungal resistance with, and transgenic plants comprising, the sarcotoxin 1a gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record set forth in the Official actions mailed 12/16/98 and 7/26/99, as applied to Claims 1-3, 5-13, 15, 16, and 18-20. Applicant's arguments filed 2/23/00 have been fully considered but they are not persuasive.

Art Unit: 1638

Applicant asserts that Applicant's failure to provide other example of anti-bacterial genes from a Diptera insect is not an adequate basis for making an enablement rejection. There is no basis in the law or in Examiner's rejection for why other examples are necessary to practice the claimed invention (response, p. 9). Examiner responds that the instant rejection is a scope of enablement rejection, not an enablement rejection. The legal basis for the rejection is that Applicant has not provided sufficient guidance to practice the claimed invention throughout the broad scope of the claims. The instant claims are broadly drawn to methods of using, and transgenic plants comprising, a DNA sequence encoding an anti-bacterial peptide from a Diptera insect. Applicant discloses a single DNA sequence which encodes an anti-bacterial peptide from a Diptera insect. Applicant does not disclose other DNA sequences encoding anti-bacterial peptides from a Diptera insect known in the prior art, nor does Applicant teach how to isolate said DNA sequences. Therefore, Examiner submits that the scope of the claims is not commensurate with the teachings of the specification.

Applicant argues that a number of other anti-bacterial peptides have been described by the prior art Wicker reference (response, p. 9-10). Examiner responds that the instant invention deploys DNA sequences, not peptides. Applicant provides no teachings of isolated DNA sequences encoding anti-bacterial peptides known in the prior art, nor guidance for how to isolate said DNA sequences in the instant specification. Therefore, the instant invention is not enabled throughout the broad scope claimed. Applicant is invited to provide evidence of the availability, at

Art Unit: 1638

the time of Applicant's invention, of other isolated DNAs encoding anti-bacterial peptides which are structurally and functionally related to the disclosed sarcotoxin 1a gene.

Further, Applicant asserts that some experimentation is allowable to practice the claimed invention, if merely routine screening. Example 7 in the specification teaches methods for screening anti-bacterial peptides for anti-fungal activity *in vitro*. Examples 8-10 describe methods for screening anti-bacterial peptides for anti-fungal activity in transgenic plants (response, p. 9-10). Examiner responds that the described screening methods are for peptides, not for DNA sequences. Further, Applicant provides no guidance for probes, primers, hybridization/wash conditions, and/or PCR reaction conditions which would allow successful isolation of DNA sequences which are structurally and functionally related to the disclosed sarcotoxin 1a gene. In the absence, of such guidance, undue trial and error experimentation would be required to screen through the vast number of cDNA or genomic clones from any Diptera insect to identify those which are related to sarcotoxin 1a, and likewise impart enhanced fungal resistance to a plant transformed therewith. The amount of experimentation which would be required to practice the claimed invention throughout the broad scope is far from routine.

Applicant also argues that listing all the possible DNAs encompassed by the claims is a practical impossibility. Nucleic acids encoding anti-bacterial peptides from a Diptera insect can be ordered from a commercial source or isolated by standard cloning techniques (response, p. 11). Examiner responds that listing of a representative sample of the DNAs encompassed by the claims is not a practical impossibility. Applicant provides no evidence of the availability of the claimed

Art Unit: 1638

DNA sequences from a commercial source. Isolation of other DNA sequences by standard cloning techniques would require undue trial and error experimentation, in the absence of appropriate guidance, for the reasons discussed *supra*.

5. Claims 21-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is unclear because all plants have some degree of resistance to pathogenic fungi. Therefore, the claim should more properly be directed to a method of increasing or enhancing resistance, as compared to an untransformed plant. Appropriate correction is required.

Claim 24 is improperly dependent on Claim 21. The claim further limits the DNA sequence, not the method. It is recommended that the claim be amended to recite --wherein said DNA sequence is in an expression vector, said expression vector comprising an expression cassette comprising said DNA sequence operably linked to a first plant promoter and a drug resistance gene operably linked to a second plant promoter--.

At Claim 24, line 6, "the first promoter" lacks proper antecedent basis, and should be changed to --the first plant promoter--.

At Claim 24, line 6, "the second promoter" lacks proper antecedent basis, and should be changed to --the second plant promoter--.

Art Unit: 1638

At Claim 25, line 3, “a hinge region” should be changed to --the hinge region-- because a chitinase gene only has a single hinge region.

At Claim 29, line 2, “a promoter” should be changed to --the promoter-- because the tobacco PR-1a gene only has one promoter.

At Claim 30, line 2, it is recommended that “has” be changed to --further comprises-- to clarify that open claim language is intended and that an additional component of the expression cassette is claimed.

At Claim 30, line 2, “a terminator” should be changed to --the terminator-- because the tobacco PR-1a gene only has one terminator.

At Claim 30, line 2, before “downstream of” --operably linked-- should be inserted to indicate that the terminator is adjacent and functionally associated with the coding sequence.

At Claim 31, “the constitutively expressed promoter” lacks proper antecedent basis.

Claim 32 is unclear because all plants have some degree of resistance to pathogenic fungi. Therefore, the claim should more properly be directed to a transgenic plant with increased or enhanced resistance, as compared to an untransformed plant. Appropriate correction is required.

At Claim 35, line 3, “a hinge region” should be changed to --the hinge region-- because a chitinase gene only has a single hinge region.

At Claim 38, line 2, “a promoter” should be changed to --the promoter-- because the tobacco PR-1a gene only has one promoter.

Art Unit: 1638

At Claim 38, line 2, it is recommended that “has” be changed to --further comprises-- to clarify that open claim language is intended and that an additional component of the expression cassette is claimed.

At Claim 38, line 2, “a terminator” should be changed to --the terminator-- because the tobacco PR-1a gene only has one terminator.

At Claim 38, line 2, before “downstream of” --operably linked-- should be inserted to indicate that the terminator is adjacent and functionally associated with the coding sequence.

At Claim 41, line 2, it is recommended that “has” be changed to --comprises-- to clarify that open claim language is intended.

Art Unit: 1638

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**AMY NELSON
PATENT EXAMINER**

Amy J. Nelson, Ph.D.

March 10, 2000